## Remarks

The Office Action mailed February 24, 2003 has been received and reviewed. Claims 7-10 and 24-27 are pending. Reconsideration and withdrawal of the rejections are respectfully requested.

### The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 9, 24, and 26, and maintained the rejection of claims 25 and 27, under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

The Action states that the specification does not support the broad scope of the claims because it does not establish (a) which regions of the protein can be modified, (b) the general tolerance of atrazine chlorohydrolases to modification and extent of such tolerances, (c) a rational and predictable scheme of modifying any amino acid of an atrazine chlorohydrolase with an expectation of obtaining the desired function, and (d) which of the essentially infinite possible choices is likely to be successful (Action, page 5 and page 7). Applicants disagree. It is not necessary to be able to predict *exactly which sequences* of a protein having 80% identity to SEQ ID NO:2 (claims 26 and 27) or encoded by a gene having a complement that hybridizes to a DNA that encodes SEQ ID NO:2 (claims 9, 24, and 25), or biologically active derivatives thereof, will maintain activity, because candidate sequences can be easily screened for atrazine chlorohydrolase activity using the assays described in the specification.

The Federal Circuit has approved of the use of screening methods to enable the production of subject matter that could not be predicted *a fortiori* to be a member of the claimed genus. In *In re Wands*, 8 U.S.P.Q.2d, 1400 (Fed. Cir. 1988) (cited by the Examiner), the court considered whether undue experimentation was required to practice an invention directed to methods for immunoassay of HbsAg using monoclonal antibodies. Specifically, the issue was whether undue experimentation was required to produce the high-affinity IgM monoclonal

antibodies used in the claimed assay, in view of experimental data that was not in dispute. *In re Wands* at 1401. It was agreed that the starting materials were publically available and the methods used to prepare hybridomas and to screen them for high-affinity IgM antibodies against HbsAg were either well known to the monoclonal antibody art or adequately disclosed. *In re Wands* at 1404. The Board agreed with the Examiner that undue experimentation was nonetheless required in order to practice the invention, citing the low success rate in obtaining hybridomas that produced the desired monoclonal antibodies. Specifically the Board found that only 4 out of 143 hybridomas tested fell within the claims, and further, that the antibodies that proved to be high-affinity IgM came from only 2 of 10 experiments. The Board thus determined that Appellant's methods were not predictable or reproducible, and concluded that the low rate of demonstrated success showed that a person skilled in the art would have to engage in undue experimentation to make antibodies that fell within the claims. *In re Wands* at 1404-1405.

The court viewed the data differently and suggested that the success rate in obtaining useful hybridomas was actually substantially better than that determined by the Board. *In re Wands* at 1406. More important, however, is the court's acknowledgment of the nature of the field of the invention and its impact on the issue of what constituted undue experimentation within the field. The court specifically recognized that monoclonal antibody technology involves screening hybridomas to determine which ones secrete the antibody with the desired characteristics, and that practitioners of that art are prepared to eliminate many negative hybridomas in order to find one that makes the desired antibody. *In re Wands* at 1406. The court further recognized that in the monoclonal antibody art, an "experiment" was viewed not simply as the screening of a single hybridoma, but is rather an entire attempt to make a monoclonal antibody against a particular antigen. The applicant showed this procedure was carried out three times, each time resulting in at least one antibody that satisfied all of the claim limitations. The court concluded that the amount of effort needed to obtain such antibodies was not excessive. *In re Wands* at 1407.

Using the legal analysis employed in *In re Wands*, it is clearly not necessary for an art worker in the field of molecular genetics to be able to predict in advance which members of a

group of candidate compounds or compositions will fall within the claimed class, as long as sufficient guidance exists to enable the art worker to screen the group and identify members of the claimed class. It is well-settled that a considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982) (copy enclosed). In the field of molecular genetics, the use of screening methods to identify and select particular molecules of interest from a heterogenous population created by random laboratory procedures or procedures having a low level of specificity or a low success rate is standard practice, and art workers are highly skilled in the use and evaluation of such screening procedures. What is required under *In re Wands* is sufficient guidance to identify and select the biological molecules that satisfy the limitations of the claims, using screening procedures available to the art or disclosed in the specification. What is *not* required under *In re Wands* is guidance regarding which regions of a sequence can be modified, the general tolerance of a sequence to modifications, a rational and predictable scheme of modifying any amino acid of a sequence with an expectation of obtaining the desired function, and which of the essentially infinite possible choices is likely to be successful.

The Examiner's attention is directed to the specification at page 10, lines 11-15, describing examples of amino acid changes that can be expected to be made to an atrazine chlorohydrolase without altering activity. It is well known in the art of protein biochemistry that polypeptides can tolerate conservative mutations at numerous sites without the elimination of protein activity. Thus, to make additional atrazine chlorohydrolase polypeptides, an art worker will need only, for example, (a) synthesize candidate proteins, or genes encoding candidate proteins; (b) sequence the candidate proteins to determine if the candidate proteins are 80% identical to SEQ ID NO:2, or synthesize genes encoding the proteins and determine if the genes hybridize to the complement of the sequence encoding SEQ ID NO:2; (c) conduct a straightforward assay (for instance, the clearing of atrazine on plates, see the specification at page 23, lines 9-16) to determine which of the candidate proteins degrade atrazine. Each of

these steps are routine in the art in view of the present specification, are within the ordinary skill of an art worker in the field, and do not involve undue experimentation.

Furthermore, it is understood that

> [T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work . . . would not serve the constitutional purpose of promoting progress in the useful arts."

M.P.E.P. §2164.08 (quoting *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976)). One of skill in the art knows that if you start with SEQ ID NO:2 and make an amino acid substitution here or there, you are very likely to end up with a sequence that also has atrazine chlorohydrolase activity. By describing SEQ ID NO:2, the Applicants have provided the art with a road map that leads directly to other active atrazine chlorohydrolases.

The Examiner is respectfully requested to reconsider and withdraw the rejection claims 9 and 24-27 35 U.S.C. §112, first paragraph, for lack of enablement.

**The 35 U.S.C. §102 Rejection**

The Examiner rejected claims 7, 9, 10, and 24-27 under 35 U.S.C. §102(a) as being anticipated by Mandelbaum et al. (*Applied and Environmental Microbiology*, 1995, *61*(4):1451-1457) as evidenced by DeSouza et al. (*Journal of Bacteriology*, 1996, *178*(16):4894-4900). This rejection is respectfully traversed.

The Action states that "[t]his 'isolated and purified' cellular extract taught by Mandelbaum et al. comprises the claimed atrazine chlorohydrolase and thus anticipates the rejected claims." The Action also quotes page 8, lines 22-25, of the specification by referring to the following: "As used herein, the terms 'isolated and purified' refer to in vitro isolation of a DNA molecule of protein from its natural cellular environment."

It is respectfully submitted that the definition of "isolated and purified" quoted above is taken out of context and is not the complete definition. The definition at page 8, lines 24-25, of the specification go on to state "so that it can be *sequenced*, replicated, and/or expressed"

(emphasis added). The proteins present in the crude cell extract taught by Mandelbaum et al. are not in a state that they can be sequenced. As further proof that the term "isolated and purified" does not include a protein present in a cell extract, the Examiner's attention is directed to page 19, line 21, of the specification which states the "AtzA protein can be isolated from cell extracts." Applicants' maintain that Mandelbaum et al. do not teach an isolated and purified protein that converts atrazine to hydroxyatrazine. As Mandelbaum et al. do not teach each element of the claim, Mandelbaum et al. does not anticipate the pending claims.

**The 35 U.S.C. §103 Rejection**

The Examiner rejected claim 8 under 35 U.S.C. §103(a) as being unpatentable over Mandelbaum et al. (*Applied and Environmental Microbiology*, 1995, *61(4)*:1451-1457) and Kennedy et al. ("Principles of immobilization of enzymes," *Handbook of Enzyme Biotechnology, 3rd Edition*, Wiseman, ed., Ellis Horwood Limited, Hertfordshire, Great Britain, Title page, publication page and pages 235-310 (1995)). This rejection is respectfully traversed.

The arguments presented in the Response mailed November 26, 2002, are maintained. The Office is also requested to note that claim 8 is dependent upon independent claim 7. If claim 7 is considered to be not obvious in view of Mandelbaum et al., then dependent claim 8 must also be considered not obvious.

## Summary

It is respectfully submitted that the pending claims 7-10 and 24-27 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for

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CERTIFICATE UNDER 37 CFR §1.10:
"Express Mail" mailing label number: EV 073735422 US Date of Deposit: May 27, 2003
The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Sam Her
Name: SAM HER

suffer from the grant of the preliminary injunction.

The balance of hardship favors plaintiff, which has at stake the alleged reputation of a brand name built up at enormous expense. If the defendant is not restrained pending trial, the alleged commercial significance of plaintiff's trademark will be undermined with resulting loss of trade and customer goodwill.

[25] Moreover, defendant's interim use of the almost identical trademark would be contrary to public interest if consumers associate a trademark with one particular producer. Then the use of that mark by another producer will mislead the public regarding the source of the merchandise. See Miller Brewing Co. v. Falstaff Brewing Corp., 503 F. Supp. 896, 208 USPQ 919 (D.P.R., 1980). Customer confusion is by its very nature against the public interest. Telledyne Industries, Inc. v. Windmere Products, Inc., 433 F. Supp. 710, 740-41, 195 USPQ 354, 378-79 (S.D. Fla., 1977).

### Breach of License Agreement

Plaintiff alleges as Count V of its complaint that defendant's acts constituted a breach of the license contract and that defendant should be compelled to pay the agreed royalties for the sales of the Chardón jeans provided by plaintiff. Defendant counterclaimed for infringement of an alleged dealer's contract executed pursuant to Puerto Rico's Act No. 75 of June 24, 1964, as amended, 10 L.P.R.A. 278, et seq., known as Puerto Rico Dealer's Contract Act. Lazoff claimed that the principal dealer relationship existing between plaintiff and defendant was wrongfully terminated by plaintiff without just cause. Even assuming arguendo that the relationship between the parties is as described by defendant, that of exclusive distributorship, the evidence showed that defendant violated the agreement in failing to pay the royalties due on the Chardón jeans and in using the trademark Chardón on other garments without the prior approval of plaintiff and without paying any royalties for the same. The evidence further shows that such violations may adversely affect plaintiff's goodwill and reputation in the trademark Chardón. Therefore, even assuming that the agreement was protected under the Puerto Rico Dealer's Act, plaintiff had just cause for terminating the same. Defendant's counterclaim must be denied.

### Conclusion

For all the foregoing reasons, plaintiff's request for preliminary injunctive relief with respect to Chardón will be *Granted*, and defendant, Lazoff Bros., Inc., its agents, servants, employees and attorneys, and all persons in active concert or participation with them, are restrained and enjoined, pending final determination of this action, from the following:

1. Using in any manner, distributing, selling, offering for sale or advertising garments bearing the Chardón trademark and/or label or any other device with reproduces counterfeits, copies or colorably initial plaintiff's trademark;

2. Committing any other acts calculated or likely to lead persons to the mistaken belief that any garment produced by defendant emanates from plaintiff or is sponsored by plaintiff, or is in any other way connected with plaintiff; and

3. Further distribution or sale of the jeans bearing the mark Chardón provided to defendant by plaintiff.

In accordance with Rule 65(c) of the Federal Rules of Civil Procedure, the preliminary injunction herein entered is to become effective upon the plaintiff's giving security in the amount of Fifty Thousand Dollars ($50,00.000), to be approved by the Court, for the payment or such costs and damages as may be incurred or suffered by the defendant in the event that it is subsequently determined that the defendant has been wrongfully enjoined.

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## Patent and Trademark Office Board of Appeals

Ex parte Jackson, Theriault, Sinclair, Fager, and Karwowski

Opinion dated Nov. 12, 1982

### PATENTS

**1. Claims — Indefinite — In general (§20.551)**

It is function of descriptive portion of specification and not that of claims to set forth operable proportions and similar process parameters and claims are not rendered indefinite by absence of recitation of such limitations.



**2. Specification — Sufficiency of disclosure (§62.7)**

Description of several newly discovered strains of bacteria having one particularly desirable metabolic property in terms of conventionally measured culture characteristics and number of metabolic and physiological properties does not enable one of ordinary skill in relevant art to independently discover additional strains having same specific, desirable metabolic property, i.e., production of particular antibiotic; in other words, verbal description of new species does not enable one of ordinary skill in relevant art to obtain strains of that species over and above specific strains made available through deposit in recognized culture depositor.

**3. Specification — Sufficiency of disclosure (§62.7)**

Sufficient information must be given in application so that one of ordinary skill in art can practice invention without necessity for undue experimentation.

**4. Specification — Sufficiency of disclosure (§62.7)**

Determination of what constitutes undue experimentation in given case requires application of standard of reasonableness, having due regard for nature of invention and state of art; test is not merely quantitative, since considerable amount of experimentation is permissible, if it is merely routine, or if specification in question provides reasonable amount of guidance with respect to direction in which experimentation should proceed to enable determination of how to practice desired embodiment of invention claimed.

**5. Specification — Sufficiency of disclosure (§62.7)**

In re Argoudelis, 168 USPQ 99, indicated that problems of enablement of processes carried out by microorganisms are uniquely different from those involved in field of chemistry generally; thus, chemistry cases such as In re Angstadt, 190 USPQ 214, and In re Geerdes, 180 USPQ 789, are inapposite to microorganism case; degree of experimentation involved in locating new microorganisms apart from deposited cultures is undue in light of enablement requirement of 35 USC 112.

**6. Plant patents (§52.)**

**Specification — Sufficiency of disclosure (§62.7)**

Statutory dispensation granted plant patent applications by 35 USC 162 from enablement requirement of 35 USC 112 does not extend to utility patent applications.

**7. Specification — Sufficiency of disclosure (§62.7)**

More detailed description of various metabolic characteristics is not sufficient to solve problems discussed in In re LeGrice, 133 USPQ 365, particularly when one considers LeGrice opinion together with subsequent remarks in In re Argoudelis, 168 USPQ 99, directly concerned with bacterial species.

**Particular patents — Antibiotic**

Jackson, Theriault, Sinclair, Fager, and Karwowski, Antibiotic AX-127B-1, rejection of claim 2 affirmed and rejection of claims 3 to 6 reversed.

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Appeal from Art Unit 125.

Application for patent of Mariana Jackson, Robert John Theriault, Arthur Charles Sinclair, Earl Elmer Clarence Fager, and James Paul Karwowski, Serial No. 008,378, filed Feb. 1, 1979. From rejection of claims 2 to 6, applicants appeal (Appeal No. 463-26). Affirmed in part; Katz, Examiner in Chief, concurring with opinion; Serota and Blech, Examiners in Chief and Seidleck, Acting Examiner in Chief dissenting in part with opinion.

Robert L. Niblack, North Chicago, Ill., for appellants.

Before Magil, Serota, Sturtevant, Milestone, Merker, Blech, Katz, and Goldstein, Examiners in Chief, and Seidleck, Acting Examiner in Chief.

Goldstein, Examiner in Chief.

This appeal is from the examiner's final rejection of claims 2 to 6. Claim 1 has been allowed. Claims 2 and 3 are reproduced below to illustrate appellents' invention.

2. A process for producing the antibiotic Ax-127B-1 which comprises culturing a microorganism belonging to the species Micromonospora pilosospora having the ability to produce antibiotic AX-127B-1 in a nutrient medium including a carbon and nitrogen source and accumulating the antibiotic in said medium.

3. A process according to claim 2 wherein said microorganism is selected from the

group consisting of Micromonospora pilosospora NRRL 11415, Micromonospora pilosospora NRRL 11416, and Micromonospora pilosospora NRRL 11417, and mutations thereof.

No references have been relied on by the examiner on appeal.

Appellants have discovered three bacterial strains which produce a new antibiotic. The antibiotic per se is the subject of allowed claim 1. Apparently on the basis of numerical taxonomy,[1] the three strains have been classified by appellants as belonging to a new species, which has been given the species name recited in the claims. All three strains have been deposited in a recognized depository and are identified in appealed claims 3-6 by their depository culture number. In claim 2, the species is recited broadly.

Claims 2 to 6 have been finally rejected under the second paragraph of 35 U.S.C. 112 as being "incomplete" for failing to recite various process parameters. We shall not affirm this rejection.

[1] It is by now well established that it is the function of the descriptive portion of the specification and not that of the claims to set forth operable proportions and similar process parameters and that claims are not rendered indefinite by the absence of the recitation of such limitations. In re Fuetterer, 50 CCPA 1453, 319 F.2d 259, 138 USPQ 217 (1963); In re Johnson, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977). Except for the specific issues discussed below, i.e., mutations and availability of the microorganism starting material, the examiner has not questioned the enabling nature of the specification.

Claims 3 to 5 have been finally rejected under the first paragraph of 35 U.S.C. 112 as being based on an insufficient disclosure of how to practice the invention claimed with respect to mutations of the recited microorganisms. It is very well known that spontaneous mutation is a common occurrence in microorganisms and that mutations can be intentionally produced by a variety of known procedures. Evidence of such knowledge in the prior art can be found in the patents cited in appellants' brief. Thus, we shall not affirm this rejection.

[2] Claim 2 has been finally rejected under the first paragraph of 35 U.S.C. 112 as being based on an insufficient disclosure with respect to the recitation Micromonospora pilosospora broadly. That is to say, the specific strains of appellants' new species of microorganism are not identified either by a deposit number as in appealed claim 3 or by a third name denominative of a specific variant strain deposited as has been done in some instances.[2] The issue squarely raised by this rejection is whether or not a description of several newly discovered strains of bacteria having one particularly desirable metabolic property in terms of the conventionally measured culture characteristics and a number of metabolic and physiological properties would enable one of ordinary skill in the relevant art to independently discover additional strains having the same specific, desirable metabolic property, i.e., the production of a particular antibiotic.[3]

To state the issue somewhat differently, it is whether a verbal description of a new species would enable one of ordinary skill in the relevant art to obtain strains of that species over and above the specific strains made available through deposit in one of the recognized culture depositories. This issue appears to be one of first impression before this Board. Furthermore, the examiners in this art do not appear to practice uniformly. That is, some appear to routinely allow claims similar in scope to appealed claim 2, while others reject them allowing only claims such as appealed claim 3. This appears to be the first application in which such a rejection was appealed to this Board. For the foregoing reasons, this appeal has been considered by an expanded panel of the Board of Appeals (see Paper No. 15 in the file). It is the carefully considered opinion of a majority of this panel that the examiner's rejection of claim 2 should be affirmed.

[3] The first paragraph of 35 U.S.C. 112 requires that the disclosure of an invention be "in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

[1] See Nester et al., Microbiology: molecules, microbes, and man (New York, Holt, Rinehart and Winston, Inc., 1973), pp. 228-229; Pelczar et al., Microbiology (New York, McGraw-Hill Book Company, 1972); pp. 50-51; Davis et al., Microbiology (Hagerstown, Maryland, Harper & Row, Publishers, Inc., 1973), p. 36.

[2] See, for example, claim 9 of Argoudelis et al., U.S. Patent No. 3,629,406, which is the patent issued on the application in suit in In re Argoudelis, 58 CCPA 769, 434 F.2d 1390, 168 USPQ 99 (1970), which will be discussed at length below.

[3] Although we do not decide this case on this narrow issue, we should note that the number of metabolic properties disclosed by appellants appears to be significantly smaller than the discussions of numerical taxonomy in the textbooks cited above would suggest are appropriate.



* * *." Decisional law has interpreted the statutory requirement as dictating that sufficient information be given in the application so that one of ordinary skill in the art can practice the invention without the necessity for undue experimentation. Fields v. Conover, 58 CCPA 1366, 443 F.2d 1386, 170 USPQ 276 (1971); In re Colianni, 561 F.2d 220, 195 USPQ 150 (CCPA 1977). Also see Ansul Co. v. Uniroyal, Inc., 448 F.2d 872, 169 USPQ 759 (2d Cir. 1971), cert. denied, 404 U.S. 1018, 172 USPQ 257 (1972). The principle that the disclosure of a patent application must enable practice of the invention claimed without undue experimentation was well established long before the enactment of the 1952 Patent Act. See Standard Brands, Inc. v. National Grain Yeast Corp., 101 F.2d 814, 40 USPQ 318 (3rd Cir. 1939), and cases cited therein.

[4] The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. Ansul Co. v. Uniroyal, Inc., supra. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. In re Rainer, 52 CCPA 1593, 347 F.2d 574, 146 USPQ 218 (1965). Also see In re Colianni, supra.

The issue in the present case relates to the amount of experimentation required to find additional strains over and above the deposited cultures, as distinguished from the presumably routine experimentation involved in determining whether a given strain once isolated produces the desired antibiotic. The landmark case in this area is In re Argoudelis, 58 CCPA 769, 434 F.2d 1390, 168 USPQ 99 (1970). The issue in that case actually was the sufficiency of a culture deposit which would not be made available to the public at large until such time as a patent issued on the application in suit. The necessity for a deposit per se was taken as an already established fact. The important aspect of the decision in that case as regards the issues in the present appeal is the statement in the opinion setting forth the policy reasons for requiring deposit in the first instance. Because of its importance, a lengthy, relevant portion of the majority opinion in that case is reproduced here.

Ordinarily no problem in this regard [i.e., the enablement requirement of 35 U.S.C. 112] arises since the method of preparing almost all starting materials can be set forth in writing if the materials are not already known and available to the workers in the art, and when this is done the specification is enabling to the public insofar as the public has access to the application under Rule 14 and 35 U.S.C. 122. *Appellants, however, because of the particular area of technology involved, cannot sufficiently disclose by written word how to obtain the microorganism starting material from nature.*

It has been pointed out in the Amicus Curiae brief that the same predicament exists in the case of asexually reproduced plants. In regard to plants, a general dispensation from the requirements of §112 has been accorded by 35 U.S.C. 162. It is urged that the same should be true here. We do not believe that a general dispensation from the statutory requirements of §112 in the case of microorganisms is necessary, desirable, or within the province of this court to grant. Our task here is not to decide what the general rule should be or to create exceptions to the provisions of §112, but rather to interpret and apply §112 to the facts of the case before us. As far as we are able to determine, an issue like the one facing us has never been decided by the courts in this country; therefore, as a matter of first impression, it requires that we analyze anew all of the statutes, law, and circumstances pertaining to this issue.

As mentioned, *a unique aspect of using microorganisms as starting materials is that a sufficient description of how to obtain the microorganism from nature cannot be given.* Such a description could only detail an experimental screening program similar to the screening programs followed in discovering the microorganism in the first instance. If the microorganism involved were of very common occurrence, it might be found in a relatively short time, but if it were not of common occurrence, it might not be found for a very long time, if found at all. The microorganism involved here, of course, was not known and available to the workers in the art since it was newly discovered by appellants. [Emphasis added] 168 USPQ at 101-102.

The above quotation illustrates that, in the opinion of the court, no general dispensation from the statutory requirements of 35 U.S.C. 112 was necessary or desirable in the case of microorganisms and that the obtention of microorganisms from nature could not be enabled by a verbal description.

The fact that appellants in this case have discovered, described and deposited three new strains whereas there was only one strain in the Argoudelis case is not seen to materially alter the situation. Discovery of a fourth strain in nature would be just as non-enabled by the description of the three deposited strains in the present specification as was the discovery in nature of the single strain at issue in Argoudelis.

Classification by appellants of the three strains under consideration as variant strains of a new species adds nothing material to the disclosure. As recognized in essentially all microbiology textbooks, bacterial classification is to a very great extent arbitrary. One such textbook states the problem succinctly as follows:

> The main unit of biological classification, the species, has no objective definition. It is, in essence, a group of organisms so similar that most experienced microbiologists would agree they are alike. But the opinions of people differ; they may place different degrees of significance upon the characteristics of an organism; the species is man-made and exists only in the mind of man.[4]

In support of their arguments for the patentability of claim 2, appellants have cited Ex parte Benedict, 111 USPQ 354 (Bd.App. 1956). The facts in that case, however, were so different from those in the present case that it can be summarily distinguished. The microorganism species recited in the appealed claims was not new but was in fact well known as was the class of antibiotics produced by the various strains of that species. In addition, appellants had asserted on the record "that *all* of the strains seem capable of elaborating the substance under proper cultural conditions" (emphasis added). 111 USPQ at 356.

**[5]** Risking redundancy, we wish to emphasize that the court in Argoudelis clearly indicated that the problems of enablement of processes carried out by microorganisms were uniquely different from those involved in the field of chemistry generally. Thus, we are convinced that such recent cases as In re Angstadt, 537 F.2d 498, 190 USPQ 214 (CCPA 1976) and In re Geerdes, 491 F.2d 1260, 180 USPQ 789 (CCPA 1974) are inapposite to this case. The experimentation involved in the ordinary chemical case, including the two cited directly above, usually arises in testing to establish whether a particular species within the generic claim language will be operable in the claimed process. As already indicated above, cases of the type before us are distinguished by the fact that the experimentation is associated with obtaining the species from nature before it can be tested. As clearly indicated in Argoudelis, the degree of experimentation involved in locating new microorganisms apart from deposited cultures is undue in light of the enablement requirement of 35 U.S.C. 112.

**[6,7]** The reasons set forth in Argoudelis as leading to a conclusion that only deposit of a new microorganism can satisfy the enablement requirement of 35 U.S.C. 112 with respect to a process utilizing that organism would appear to be entirely dispositive of the issue in the present case. Nonetheless, independent consideration of In re LeGrice, 49 CCPA 1124, 301 F.2d 929, 133 USPQ 365 (1962) (cited in Argoudelis) may shed additional light on the issue. At issue in that case was the rejection of a plant patent application under 35 U.S.C. 102(b). In its relevant aspect, that case dealt with the effect as a reference of a verbal description of a plant in a printed publication. The court held that a particular plant was not placed in the possession of the public, i.e., its obtainment, was not enabled, by a verbal description.[5] Although unicellular organisms are no longer generally classified as members of the plant or animal kingdom but are now considered to form a distinct kingdom of their own (Protista [6]), the similarities in the problems of providing an enabling verbal disclosure are manifest. We do not think that the more detailed description here, i.e., various metabolic characteristics, is sufficient to solve the problems discussed in the opinion in LeGrice, particularly when one considers the LeGrice opinion together with the subsequent remarks of the court directly concerned with bacterial species in Argoudelis.

The examiner's rejection of claim 2 is affirmed. The examiner's rejection of claims 3 to 6 is reversed.

*Affirmed-in-part*

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Katz, Examiner-in-Chief, concurring.

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[4] Pelczar et al., Op. cit., p. 49. See also Davis et al., Op. cit., pp. 35-36; Nester et al., Op. cit., pp. 226-228.

[5] As discussed above at page 6, the statutory dispensation granted plant patent applications by 35 U.S.C. 162 from the enablement requirement of 35 U.S.C. 112 does not extend to utility patent applications.

[6] Nester et al., Op. cit., pp. 52-53.



I fully agree with the conclusions reached by the majority and add the following only in response to the position taken in the dissenting opinion.

The dissent states that appellants have fully complied with the enablement requirements of the first paragraph of section 112 in that the specification describes certain physical attributes of the species and have also functionally described the species.

Since there is clear exemplary support in the specification, as filed, for the claim language, it would normally be held as set forth in In re Moore, 58 CCPA 1042, 439 F. 2d 1232, 169 USPQ 236 (1971), and In re Geerdes, 491 F. 2d 1260, 180 USPQ 789 (CCPA 1974), that the specification is commensurate in scope with the breadth of the claims and is sufficient to support the claims and satisfy the "how to make and use" requirement of section 112.

However, claims to the use of microorganisms are unique and should not be judged in the same manner as chemical processes or mechanical procedures. Claim 2 requires, as the essential component, the use of a microorganism belonging to a defined species which can produce the described antibiotic. One skilled in this art, as clever and innovative as he may be, cannot find or produce, on demand, the organisms necessary for use in the claimed process. Even considering the newly developing biological engineering techniques, at this time it is just not feasible to expect one skilled in the art to "manufacture" the necessary microbe. In order to produce the specific antibiotic described it would be necessary to obtain a sample of the particular named strain from the depository where pure cultures of the named bacteria are maintained. The fact that three specific varieties are available would not allow one to extrapolate or experiment to obtain a fourth strain. No biological expertise or other scientific skill will "enable" one to produce a fourth strain capable of carrying out the invention, except by mutation of one of the deposited strains. In other words, mere description in words will not enable one to make or find the named microorganisms.

Accordingly, the fact that the specification defines the microbe in language as broad as that recited in the claims should not, due to the special circumstances relating to bacteria, function, on that basis alone, as support for coverage of undisclosed strains of bacteria. As recited in MICROBIOLOGY, * at page 49:

> The main unit of biological classification, the species, has no objective definition. It is, in essence, a group of organisms so similar that most experienced microbiologists would agree they are alike. But the opinions of people differ; they may place different degrees of significance upon the characteristics of an organism; the species is man-made and exists only in the mind of man.

Thus, what appellants define as "their" disclosed species may have no practical value insofar as defining the group of useful microorganisms.

Appellants have defined three strains of organisms. These have been cultured and purified and finally tested for the manufacture of antibiotic AX-127B-1. Insofar as the disclosure is concerned, *only* these three strains of organisms have been shown to be suitable. It is mere conjecture to assume that other strains of the broader species are capable of such action. In fact, the field of microbe discovery is very unscientific at its initial stages. Samples of soil and other bacterial habitats are collected from different parts of the world and tested to determine what products may be produced under different conditions. This method of investigation is very precise, but the results are not predictable. At times the least likely source of microbes will contain one strain, from a mixture of millions of strains, which will give rewarding results. When we couple this with the fact that each sample from any part of the earth may contain literally a jungle of many different organisms, we can appreciate that there is no way of predicting when a useful bacteria will be found. The results are more a matter of luck, not skill.

As stated in In re Argoudelis et al., 58 CCPA 769, 434 F. 2d 1390, 168 USPQ 99 (1970), at page 102:

> If the microorganism involved were of very common occurrence, it might be found in a relatively short time, but if it were not of common occurrence, it might not be found for a very long time, *if found at all* (emphasis added).

The microorganisms involved here, as in Argoudelis et al., were not known and available to the workers in the art, since they were newly discovered by appellants. The unnamed and undisclosed organisms which may belong to the species defined by appellants may or may not exist and may or may not be found. Then, if found, they may not have the antibiotic producing properties ascribed to the three discovered strains.

The dissent also takes the position that appellants should be entitled to generic protection since the "mere amount of time" nec-

* Pelczar et al., Microbiology (New York, McGraw-Hill Book Company, 1972), p. 49.

essary to locate a suitable microorganism should not be fatal.

I believe that the position of the dissenters has some merit in certain instances, but cannot be relied on as a broad-brush approach to the subject.

Some bacterial processes are so basic and pervasive, such as the fermentation of sugar to alcohol, the action of yeast on starch and the fixation of nitrogen, that the skilled person would have no difficulty in reaching the conclusion that all members of the species, even undiscovered members, would have the described basic property of the strains being worked on. While, it is not likely that all of the microorganisms of the species would be equally efficient and suitable under the same conditions of temperature and concentration, they would likely function to give the described result. In such situations, I agree with the dissent that generic coverage should not be excluded. However, here we are dealing with an esoteric function of novel bacteria used to manufacture a novel antibiotic. One skilled in this art would have no way of finding, on demand, the other members of the species, and there is no showing in the record to provide a suitable basis for assuming that any antibiotic AX-127B-1 would be produced by the other members of the designated species.

Accordingly, I do not believe that a general rule of law can be made as to compliance with section 112. Each case must be examined to determined the type of organism, the metabolic reactions involved, and the evidence developed as to universality of properties of the claimed organisms.

In the situation before us, I remain unconvinced that the described processes are so conventional and predictable that one would reasonably expect that all members of the species, although not yet discovered, would form the named antibiotic.

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Serota, Examiner-in-Chief, dissenting-in-part, joined by Blech, Examiner-in-Chief and Seidleck, Acting Examiner-in-Chief.

We do not agree with our colleagues' conclusion that the present specification does not comply with the enablement requirements of the first paragraph of 35 U.S.C. 112. The appellants have described certain physical attributes of the species and also have functionally described the species ("having the ability to produce* * *."). In addition, the appellants have deposited three strains of the microorganism. This, under the circumstances, would appear to adequately satisfy the statutory description and enablement requirements. The worker in the art is told what physical and functional characteristics are required of the microorganism. This would appear to be sufficient under the guidelines set down by our principal reviewing court in such cases as In re Angstadt, 537 F. 2d 498, 190 USPQ 214 (CCPA 1976); In re Dinh-Nguyen, 492 F. 2d 856, 181 USPQ 46 (CCPA 1974); In re Bowen, 492 F. 2d 859, 181 USPQ 48 (CCPA 1974); In re Geerdes, 491 F. 2d 1260, 180 USPQ 789 (CCPA 1974). We note that there is here no assertion that one skilled in the art would not recognize whether a particular microorganism is within or without the claimed species; the allegation is that it may take some time to locate a microorganism not derived from one of the three deposited strains. We do not believe that the mere amount of time which may be necessary is fatal. If the position of the majority is correct, and applicant would almost never be entitled to generic protection, but would almost always be limited to specific strains deposited. This would appear to be an unduly restrictive interpretation of the statutory requirements. We would, therefore, reverse this rejection.

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**Patent and Trademark Office**
**Trademark Trial and Appeal Board**

Electronic Realty Associates, Inc.
v. Extra Risk Associates, Inc.

Decided May 28, 1982

**TRADEMARKS**

**1. Defenses — Fraud (§30.05)**

Allegations of fraud are serious allegations; they must be pled with particularity and are subject to heavy burden of proof.

**2. Defenses — Fraud (§30.05)**

Fraudulent intent is absolutely essential element of any fraud claim.

**3. Defenses — Fraud (§30.05)**

Mere fact that applicant had prior knowledge of mark that is similar to, or same as, mark for which it applied to register does not constitute fraud or even raise fraud issue where there is arguable difference between applicant's mark and mark of registration; inference of fraudulent intent is unwarranted in such circumstances.



**4. Class of goods — In applications to register (§67.205)**

TTAB is constrained to determine likelihood of confusion issue on presumption that services are as they are identified in application for registration even where record evidence is inconsistent with such identification.

**5. Acquisition of marks — In general (§67.071)**

Intention to use mark in future does not create any rights.

**6. Opposition — Mark and use of opposer—In general (§67.5831)**

Opposer cannot rely on its subsequent expansion into new field to bridge gap of dissimilarity when that expansion took place following applicant's establishment of rights in its mark.

**7. Identity and similarity — How determined — Descriptive or disclaimed matter (§67.4061)**

Likelihood of confusion issue must be resolved based on consideration of marks in their entireties, including matter that has been disclaimed; it is mark sought to be registered, that is, as it is displayed in drawing, that is controlling.

**8. Class of goods — Particular cases — Not similar (§67.2071)**

Real estate brokerage services and substandard insurance services are not sufficiently related that purchasers would be likely to assume their common source or origin when offered contemporaneously under similar marks.

**9. Opposition — Pleading and practice (§67.589)**

To prevail under Lanham Act section 2(a), opposer must, at very least, demonstrate that there is likelihood of confusion under same standards as those that are applied under section 2(d); opposer that has not established its claim under section 2(d) cannot possibly prevail based on section 2(a) irrespective of whether further requirements of claim of deceptiveness have been met.

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Trademark Opposition No. 62,309, by Electronic Realty Associates, Inc., against Extra Risk Associates, Inc., application, Serial No. 149,704, filed Nov. 23, 1977. Opposition dismissed.

Lowe, Kokjer, Kircher, Wharton & Bowman, Kansas City, Mo., for Electronic Realty Associates, Inc.

Berman, Aisenberg & Platt, Washington, D.C., for Extra Risk Associates, Inc.

Before Rice, Allen, and Simms*, members.

Allen, Member.

Extra Risk Associates, Inc., assignee of C. Stanton MacDonald, d.b.a. Extra Risk Associates, filed an application for registration of the mark "ERA EXTRA RISK ASSOCIATES" for insurance brokerage services for substandard underwriting in the life, health, accident and disability insurance fields. In its application, MacDonald alleges use of its mark since September 1, 1975. The words "EXTRA RISK ASSOCIATES" have been disclaimed.

Electronic Realty Associates, Inc. has opposed registration, alleging prior use and registration of the mark "ERA" in respect of real estate brokerage services;[1] prior use of "ERA" in connection with insurance services; that the mark sought to be registered by applicant is so similar in sound, meaning and appearance to opposer's mark as to be likely, when applied to the services of the applicant, to cause confusion, deception or mistake of the purchasing public; that registration of the mark is prohibited under Section 1 of the Trademark Act since applicant is not its owner; that applicant is guilty of committing fraud on the Patent and Trademark Office in view of its knowledge of opposer's rights in and to the mark "ERA" prior to filing its application for registration; and that the mark "ERA EXTRA RISK ASSOCIATES" falsely suggests a connection with opposer and, thus, is unregistrable pursuant to Section 2(a)

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* Board Member Simms has been designated to substitute for Member Kera who resigned from government service before an opinion was drafted in this case and did not participate in the resolution of any of the issues herein or in the decision.

[1] Attached to the notice of opposition were status copies of three registrations indicating title in opposer, as follows: "ERA" for real estate brokerage services, Reg. No. 1,078,060, issued November 22, 1977; "ERA & DESIGN" for "providing electronic realty listing services whereby potential purchasers can view pictures transmitted by wire of property located in various cities and whereby sellers can transmit pictures of their property to potential purchasers in other cities," Reg. No. 1,057,923, issued February 1, 1977; and "ERA AND DESIGN" for the same services as those indicated above (in respect of Reg. No. 1,057,923) Reg. No. 1,003,531, issued January 28, 1975.